IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ADRIENNE RICHIE and JASON RICHIE	§	
Plaintiffs,	§	
	§	
v.	§	**CIVIL ACTION NO. 1:17-cv-05529**
	§	
NOVO NORDISK INC.,	§	
Defendant.	§	

DEFENDANT NOVO NORDISK INC.'S
ANSWER TO PLAINTIFFS' ORIGINAL COMPLAINT

Defendant Novo Nordisk Inc.[1] ("Defendant"), by and through its counsel, hereby says in answer to Plaintiffs' Original Complaint:

Allegations Common to All Counts

1. **Allegation:** On October 3, 2015, and at all times relevant herein, the Plaintiff, Adrienne Richie, was a resident of the City of Chicago, County of Cook, State of Illinois.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

2. **Allegation:** On October 3, 2015, and at all times relevant herein, Defendant Novo Nordisk, Inc., was an [*sic*] foreign corporation, registered in Illinois, with principal place of business being in Delaware.

Answer: Novo Nordisk Inc. admits that it is registered to do business in the state of Illinois and, by way of further answer, states that its principal place of business is located at 800 Scudders Mill Road, Plainsboro, NJ 08536. Except as admitted, denied.

[1] Incorrectly captioned and referred to in Plaintiffs' Original Complaint as "Novo Nordisk, Inc."

3. **Allegation:** On and about October 3, 2015, and at all relevant times herein, the Defendant, Novo Nordisk, Inc., was in the business of manufacturing and selling pharmaceutical products and applicator devices for said pharmaceutical products.

Answer: Novo Nordisk Inc. admits that its business includes activities relating to the marketing of FDA-approved prescription medications. Except as so admitted, denied.

4. **Allegation:** More specifically, on and about October 3, 2015, and at all times relevant herein, Defendant, Novo Nordisk, Inc., designed and manufactured a type of product known as the NovoLog FlexPen, prefilled syringe.

Answer: Defendant admits that one of the products it marketed on and about October 3, 2015, was the NovoLog® FlexPen®. Defendant states by way of further answer that NovoLog® is an FDA-approved rapid acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus, and that, as reflected in the FDA-approved prescribing information, the NovoLog® is sometimes delivered via an FDA-approved pre-filled insulin pen called the NovoLog® FlexPen®. Except as so admitted, denied.

5. **Allegation:** At all times relevant herein, Defendant Novo Nordisk, Inc., was engaged in the manufacturing, labeling, marketing, distributing, promoting, testing, and selling of NovoLog FlexPen, prefilled syringes.

Answer: Defendant admits it has engaged in activities related to the marketing of NovoLog® and NovoLog® FlexPen® in the United States, and, by way of further answer, that NovoLog® is an FDA-approved prescription medication for the treatment of diabetes mellitus. Except as so admitted, denied.

6. **Allegation:** On and about October 3, 2015, and at all times relevant herein, the aforementioned product was sold in the State of Illinois by various pharmacies, by prescription only.

Answer: Defendant admits that NovoLog® is an FDA-approved prescription medication that was marketed by Defendant in October of 2015, including sales of the product in Illinois. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

7. **Allegation:** On and about October 3, 2015, and at all times relevant herein, Defendant Novo Nordisk [*sic*], sold its NovoLog FlexPen, at CVS retail pharmacies in the City of Chicago, County of Cook, State of Illinois.

Answer: Defendant admits that it marketed NovoLog® and NovoLog® FlexPen®, including sales in the state of Illinois, in October of 2015. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

8. **Allegation:** On and about October 3, 2015, and at all times relevant, the Plaintiff, Adrienne Richie suffered from juvenile onset diabetes, managed through prescription medications, including the product made by the Defendant Novo Nordisk, Inc.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

9. **Allegation:** More specifically, on and about October 3, 2015, the Plaintiff would take insulin dosage of 4 units before breakfast, lunch, and dinner.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

10. **Allegation:** On and about October 3, 2015, and at all times relevant herein, the Plaintiff, Adrienne Richie, suffered from peripheral neuropathy, limiting sensation and feeling in her hands.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

11. **Allegation:** On or about June 11, 2015, CVS Health Corporation, (hereinafter, "CVS Pharmacy") filled a prescription for Adrienne Richie, script no. 1032857, for Novolog [*sic*] 100 units/ML Flexpen [*sic*], manufactured and distributed by Defendant, Novo Nordisk, Inc.

Answer: Defendant admits that it marketed NovoLog® and NovoLog® FlexPen® in 2015. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

12. **Allegation:** More specifically, on June 11, 2015, CVS Pharmacy provided the Plaintiff, Adrienne Richie, multiple pre-packaged Novolog [*sic*] 100 units/ML flexpens [*sic*], pursuant to her prescription.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

13. **Allegation:** On or about October 3, 2015, the Plaintiff, Adrienne Richie, removed from the package and began using Novolog [*sic*] FlexPen Prefilled Syringe, Control No.: EZF0052, with an expiration date of April, [*sic*] 2017.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

14. **Allegation:** At all times relevant herein, Defendant, Novo Nordisk, Inc., held out that it's [*sic*] Novolog [*sic*] FlexPen Prefilled Syringes were fit for human use and that they performed pursuant to product specifications.

Answer: Defendant states that it is unclear what Plaintiff intends in referring to Defendant "holding out" a product as having characteristics, and on that basis Defendant lacks sufficient knowledge to respond. By way of further answer, Defendant states that it performed adequate and thorough pre-clinical and clinical testing of NovoLog® and NovoLog® FlexPen®, leading to its approval by the FDA as safe and effective and reflected by the FDA-approved prescription information. Except as so admitted, denied.

15. **Allegation:** On October 3, 2015, and at all times relevant herein, Novolog [*sic*] Flex Pen [*sic*], control No [*sic*] EZF0052 was defective in that its injector did not function as promised.

Answer: Denied.

16. **Allegation:** More specifically, and unbeknownst to the Plaintiff, Adrienne Richie, when she would set her dosage and push the injector, as she had numerous other times with other syringes of the same product, minimal to no dosage of insulin would be released.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

17. **Allegation:** On October 3, 2015, and at all times relevant herein, as a function of her neuropathy, the Plaintiff Adrienne Richie, was unable to appreciate that Novolog [*sic*] Flex Pen [*sic*] control no. EZF0052, was not administering a sufficient dosage of insulin.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

18. **Allegation:** As a direct and proximate result of the failure of the Novolog [*sic*[Flex Pen [*sic*] to administer the selected dosage, the Plaintiff, Adrienne Richie, was unable to control her blood sugar, and suffered from multiple diabetic crises, including coma with organ involvement.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

Count I: Negligence

19. **Allegation:** Plaintiff realleges and incorporates by reference paragraphs 1 through 18 as if fully set out in this Count I.

Answer: Defendant incorporates by reference all of its responses to Plaintiff's allegation in paragraphs 1 through 18.

20. **Allegation:** On October 3, 2015, and at all times relevant herein, the Defendant, Novo Nordisk, Inc., had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, and distribution of the Novolog [*sic*] FlexPen Prefilled Syringe, so that said product would perform in accordance with its FDA approval for products that the Defendant introduced into the stream of commerce, including a duty to ensure that users would not receive defective and/or unusable products.

Answer: Defendant admits that certain duties arise or exist by operation of law, but denies breaching any such duties related to NovoLog® and NovoLog® FlexPen®. Otherwise, Defendant denies the allegations in this paragraph.

21. **Allegation:** At all times relevant herein, the Defendant knew, or through the exercise of reasonable care, should have known, that the NovoLog FlexPen, control no. EZF0052 was defective in that it failed to dispense medication as specified.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

22. **Allegation:** The Plaintiff first became aware of the defective nature of the NovoLog Flex Pen [*sic*] control no. EZF0052 after her discharge from the hospital in October 2015.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

23. **Allegation:** At all times relevant, Defendant Novo Nordisk, Inc., placed a defective product in the stream of commerce, in that it did not perform to its approved specifications.

Answer: Denied.

24. **Allegation:** At all times relevant herein, Defendant Novo Nordisk, Inc., failed to warn the Plaintiff, who suffers from neuropathy that impacts the sensation in her fingers, that its injecting device may fail.

Answer: Defendant denies that its product was defective. Defendant further denies that under Illinois law it has any duty to warn patients directly, but refers to the FDA-approved prescribing information, which speaks for itself. Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

25. **Allegation:** The Plaintiff's damages are in excess of $50,000.00, the minimal jurisdictional limit for the Law Division, Circuit Court of Cook County.

Answer: Defendant denies that Plaintiff is entitled to damages or any other relief.

Demand: WHEREFORE, the Plaintiff, Adrienne Richie, prays for judgment in her favor and against Defendant Novo Nordisk, Inc., for past and future medical expenses, past and future pain and suffering, past disability, past and future medical, drug and incidental expenses, general damages according to the proof and for any other relief this Court deems just.

Answer: Defendant denies that Plaintiff is entitled to damages or any other relief.

Count II: Breach of Warranty of Merchantability-Express

II-19[2]. **Allegation:** Plaintiff realleges and incorporates by reference paragraphs 1 through 18 as if fully set out in this Count II.

Answer: Defendant incorporates by reference all of its responses to Plaintiff's allegations in paragraphs 1 through 18.

II-20. **Allegation:** Defendant Novo Nordisk, Inc., manufactured and/or distributed the aforementioned Novolog [*sic*] FlexPen, control ID, EZF0052, knowing that CVS Pharmacy would place it in the stream of commerce without modification or alteration.

[2] Plaintiffs re-started the paragraph numbering with each new Count. To keep the paragraphs distinct, Defendant will, starting with this paragraph, put the Count number before each paragraph number.

Answer: Defendant admits that it marketed the FDA-approved medication Novolog® and the NovoLog® FlexPen®. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

II-21. **Allegation:** The aforementioned item was not fit for the ordinary purpose said package of NovoLog FlexPens were sold for.

Answer: Denied.

II-22. **Allegation:** Further, there was no warning on said product or packaging indicating that the product may not perform to specification.

Answer: Defendant refers to the FDA-approved prescribing information for NovoLog® and the NovoLog® FlexPen®, which speaks for itself. Except as admitted, denied.

II-23. **Allegation:** Novolog FlexPen Control ID EZF0052 did not perform to the specification of the injector aspect of said product.

Answer: Denied.

II-24. **Allegation:** The Plaintiff, Adrienne Richie, had a reasonable expectation of uniformity of her NovoLog FlexPens so that each use dispensed the specific amount of medication the dial was set for.

Answer: This allegation calls for a legal conclusion to which a response is not required. Defendant admits that the NovoLog® FlexPen® is, as reflected in the FDA-approved labeling, a disposable dial-a-dose insulin pen permitting the user to select doses in increments of 1 unit. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

II-25. **Allegation:** During use, and unbeknownst to Adrienne Richie, Novolog [*sic*] FlexPen Control ID EZF0052, did not dispense the proper amount of insulin.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

II-26. **Allegation:** As a direct and proximate result of the failure of the Novolog [*sic*] Flex Pen [*sic*] to administer the selected dosage, the Plaintiff, Adrienne Richie, was unable to control her blood sugar, and suffered from multiple diabetic crises, including coma with organ involvement.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

Count III: Strict Liability

III-19. **Allegation:** Plaintiff alleges and incorporates by reference paragraphs 1 through 18 as if fully set out in this Count II [*sic*].

Answer: Defendant incorporates by reference all of its responses to Plaintiff's allegations in paragraphs 1 through 18.

III-20. **Allegation:** As a direct and proximate result of the defendant's product failing to perform to its specifications, the Plaintiff was injured.

Answer: Denied.

III-21. **Allegation:** The Plaintiff's injury was caused by a defective and therefore unreasonable dangerous condition of the Defendant's product in that it did not dispense essential medication as specified.

Answer: Denied.

III-22. **Allegation:** The defective condition of the NovoLog Flex Pen [*sic*], control No.: EZF0052, existed at the time it left the manufacturing facilities of Defendant Novo Nordisk, Inc.

Answer: Denied.

Demand: WHEREFORE, the Plaintiff, Adrienne Richie, prays for judgment in her favor and against Defendant Novo Nordisk, Inc., for past and future medical expenses, past and future pain and suffering, past disability, past and future medical, drug and incidental expenses, general damages according to the proof and for any other relief this Court deems just.

Answer: Defendant denies that Plaintiff is entitled to damages or any other relief.

Count IV: Loss of Consortium

IV-1-18. **Allegation:** Plaintiff Jason Richie realleges and incorporates paragraphs 1-18 of Count I as if fully set out in this Count IV.

Answer: Defendant incorporates by reference all of its responses to Plaintiff's allegations in paragraphs 1 through 18.

IV-19. **Allegation:** At all times relevant herein, the Plaintiff, Jason Richie, is, and has been the loving husband of the Plaintiff, Adrienne Richie.

Answer: Defendant is without knowledge or information sufficient to form a belief as to the allegations in this paragraph.

IV-20. **Allegation:** By reason of the wrongful conduct of Defendant Novo Nordisk, Inc., and resulting injuries therefrom, the Plaintiff, Jason Richie, has been deprived of the type of consortium, society, affection, and other losses he was accustomed to from his wife, Plaintiff Adrienne Richie, before this occurrence.

Answer: Defendant denies that its product was defective. Defendant is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph.

Demand: WHEREFORE, the Plaintiff, Jason Richie, prays for judgment in his favor and against the Defendant Novo Nordisk, Inc., for loss of consortium, society, affection, and other losses, and any other relief this Court deems appropriate.

Answer: Defendant denies that Plaintiff Jason Richie is entitled to damages or any other relief.

AFFIRMATIVE AND OTHER DEFENSES

Having answered the allegations in Plaintiffs' Original Complaint and having denied any liability, Defendant further denies any allegations that have not been expressly admitted. Defendant has only just begun investigating Plaintiff's claims; discovery and investigation may reveal that any one or more of the following defenses should be available to Defendant in this matter. Defendant therefore asserts said defenses in order to preserve the right to assert them. By asserting the matters set forth below, Defendant does not allege or admit that it has the burden of proof or the burden of persuasion with respect to any of these matters. Further, Defendant reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds.

Further answering and by way of additional defense, Defendant states as follows:

1. Each and every claim alleged or raised in the Original Complaint is barred by the learned intermediary doctrine.

2. Each and every claim alleged or raised in the Original Complaint is barred by the doctrines of statutory and regulatory compliance.

3. If Plaintiff has sustained injuries or losses as alleged in the Original Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening and/or supervening cause or causes.

4. Upon information and belief, Plaintiff's alleged injuries and damages, if any, were caused by the acts or omissions of Plaintiff, and/or by the fault of Plaintiff, and/or by her assumption of risk, and thus any recovery might be reduced accordingly or eliminated altogether in accord with applicable statutes and common law, including the law of Illinois (735 Ill. Comp. Stat. Ann. 5/2-1116).

5. In the alternative, without waiving its denial of liability to Plaintiff, Defendant states that any fault on the part of Defendant (which Defendant expressly denies) in proximately causing any injury or damage Defendant is only severally liable, if at all, for all damages except past and future medical and medically-related expenses.

6. If Plaintiff has sustained injuries or losses as alleged in the Original Complaint, upon information and belief, such injuries and losses were proximately caused by misuse or abuse of the product at issue, or by a substantial change in the product after leaving the possession, custody, and control of Defendant.

7. If Plaintiff has sustained injuries or losses as alleged in the Original Complaint, upon information and belief, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions, or natural courses of conditions for which Defendant is not responsible.

8. Each and every claim alleged or raised in the Original Complaint is barred because the product at issue was made in accordance with the state of the art at the time it was manufactured.

9. Plaintiff cannot establish that any reasonable alternative design would have rendered the product at issue safer overall, and that the failure to adopt a reasonable alternative design rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Product Liability.

10. Plaintiff cannot establish that any reasonable alternative instructions or warnings concerning foreseeable risks of harm posed by the product at issue would have rendered the product safer overall, and that the failure to provide such alternative instructions or warnings rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

11. Each and every claim alleged or raised in the Original Complaint is barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

12. Each and every claim alleged or raised in the Original Complaint is barred in whole or in part because legally adequate "directions or warnings" were provided as to the use of the product at issue and any other medicine or pharmaceutical preparation to which Plaintiff attributes her alleged damages within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

13. Each and every claim alleged or raised in the Original Complaint is barred by Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

14. Each and every claim alleged or raised in the Original Complaint is barred by comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

15. The common law claims and theories of liability set forth in the Original Complaint are barred by the doctrine of federal preemption. Defendant's conduct conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations, and there is clear evidence that any warnings proposed by Plaintiff would not have been permitted by the FDA. Accordingly, each and every claim alleged or raised in the Original Complaint is barred in whole or in part under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

16. Each and every claim alleged or raised in the Original Complaint is barred because, if the product at issue was unsafe, which Defendant denies, then it was unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of that product exceeded any apparent risk, given the scientific knowledge available when the product was marketed.

17. Plaintiff's damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiff as a result of any insurance or other health benefits plan, or any amounts paid for by any insurance, other health benefits plan, or other collateral sources. Defendant requests application of the modified Collateral Source Rule as set forth in the statute limiting economic damages for medical expenses to the amounts actually paid to a healthcare provider.

18. Plaintiff's claims are barred, reduced, or limited pursuant to applicable statutory and common law regarding limitations of awards and caps on recovery.

WHEREFORE, Defendant respectfully demands judgment dismissing the Original Complaint with prejudice and awarding Defendant such other and further relief that the Court may deem just and proper.

JURY DEMAND

Defendant demands a trial by jury as to all issues so triable.

Date: August 4, 2017

Respectfully submitted,

BOWMAN AND BROOKE LLP

By: *s/Sandra Giannone Ezell*
Sandra Giannone Ezell (IL # 6205035)
901 East Byrd Street, Suite 1650
Richmond, Virginia 23219
(804) 649-8200
(804) 649-1762 [Facsimile]
sandra.ezell@bowmanandbrooke.com

COUNSEL FOR DEFENDANT NOVO NORDISK INC.

CERTIFICATE OF SERVICE

On August 4, 2017, I electronically submitted the foregoing document for filing with the Clerk of the United States District for the Northern District of Illinois, Eastern Division, using the electronic case filing system of said court. I hereby certify that I have forwarded the same to Plaintiffs' counsel on the same date by certified mail, return receipt requested, at the following address:

Erron H. Fisher, Esq.
Fisher & Lamonica, P.C.
100 S. Wacker Drive, Ste. 1160
Chicago, IL 60606

s/ Sandra Giannone Ezell